



AUG -2 2004

Adrian G. Looney  
Pfizer Inc.  
Legal Division  
150 East 42nd Street  
New York NY 10017-5755

Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,567,817

### NOTICE OF FINAL DETERMINATION and REQUEST FOR ASSIGNMENT INFORMATION

A determination has been made that U.S. Patent No. 5,567,817, which claims the human drug product VFEND® (voriconazole) and the method of use of said product, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 945 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 945 days.

If the patent term extension were calculated according to 35 U.S.C. § 156(c) using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of April 18, 2003 (68 Fed. Reg. 19212), the extension would be:

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (1,898 - 411) + 554 \\ &= 1,298 \text{ days}\end{aligned}$$

Since the regulatory review period began September 8, 1995, before the patent issued (October 22, 1996), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From September 8, 1995 to and including October 22, 1996 is 411 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,298 days, would extend the patent from October 22, 1996 (35 U.S.C. § 154) to May 12, 2017, which is beyond the 14-year limit (the approval date is May 24, 2002, thus the 14 year limit is May 24, 2016). The period of extension is thus limited to May 24, 2016, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of

extension is the number of days to extend the term of the patent from its original expiration date, October 22, 2013, to and including May 24, 2016, or 945 days.

The limitations of 35 U.S.C. § 156 (g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,567,817
Granted:	October 22, 1996
Original Expiration Date <sup>1</sup> :	October 22, 2013
Applicant:	Stephen J. Ray, et al.
Title:	Triazole Antifungal Agents
Classification:	544/333
Product Trade Name:	VFEND® (voriconazole)
Term Extended:	945 days
Expiration Date of Extension:	May 24, 2016

**A review of the assignment records reflects an assignment of the great-grand parent application, Application No. 07/646,564 from Pfizer Limited to Pfizer Inc., but no assignment from the inventors has been located. The name of the assignee will be reflected on the patent term extension certificate and Official Gazette Notice if applicant provides a copy assignments in the full chain of title for the above-identified patent.**

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Mail Stop Patent Ext. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450.	By FAX:	(703) 872-9411
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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin L. Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane  
Rockville, MD 20857

Attention: Claudia Grillo

RE: VFEND  
FDA Docket No. : 03E-0031